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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

4240-142 In re United States Patent Application of: Docket No.: Conf. No.: 1480 Applicants: LEE, Sang Yup, et al. 1652 Art Unit: Application No.: 10/580,556 Examiner: Mohammad Y. Meah Date Filed: May 26, 2006 **NOVEL RUMEN BACTERIA** Customer No.: Title: VARIANTS AND PROCESS 23448 FOR PREPARING SUCCINIC ACID EMPLOYING THE SAME

FACSIMILE TRANSMISSION CERTIFICATE ATTN: Examiner Mohammad Y. Meah Fax No. (571) 273-8300

I hereby certify that this document is being filed in the United States Patent and Trademark Office, via facsimile transmission, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, and transmitted on the date specified below, to United States Patent and Trademark Office facsimile transmission number (571) 273-8300.

Number of linges

Kate Pope

May 30, 2007

Date

RESPONSE TO APRIL 30, 2007 RESTRICTION REQUIREMENT IN U.S. PATENT APPLICATION NO. 10/580,556

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Sir:

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This responds to the April 30, 2007 Requirement for Restriction in the above-identified application. In the Requirement for Restriction dated April 30, 2007, the Examiner has required restriction under the provisions of 35 U.S.C. §121 among:

- Group I, claims 1 and 4-7, drawn to rumen bacterial mutant having ldhA and pfl gene disrupted to increase succinic acid production;
- Group II, claims 2, 8-9, and 31-31[sic 32 apparently intended], drawn to rumen bacterial mutant having ldhA and pfl gene, pta gene and ackA gene disrupted to increase succinic acid production;
- Group III, claims 3, 10, and 33-34, drawn to rumen bacterial mutant having ldhA and pfl
 gene and ppc gene disrupted to increase succinic acid production;
- Group IV, claims 11, and 15-17, drawn to method of producing mutant of group I by mutating ldhA and pfl gene;
- Group V, claims 12, 14, and 18-20, drawn to method of producing a mutant of group II by mutating *ldhA* and *pfl* gene, *pta* gene and *ackA* gene.
- Group VI, claims 13, 21-23, and 35, drawn to method of producing a mutant of group III by mutating *ldhA*, ppc and pfl gene.
- Group VII, claim 24, drawn to vector comprising disrupted ldhA gene.
- Group VIII, claim 25, drawn to vector comprising disrupted pfl gene.
- Group IX, claim 26, drawn to vector comprising disrupted pta and ackA gene.
- Group X, claim 27, drawn to vector comprising disrupted ppc gene.
- Group XI, claims 28-30, drawn to method of producing succinic acid using rumen bacterial mutant having ldhA and pfl gene disrupted.
- Group XII, claims 28-30, drawn to method of producing succinic acid using rumen bacterial mutant having *ldhA* and *pfl* gene, *pta* gene and *ackA* gene disrupted.
- Group XIII, claims 28-30, method of producing succinic acid using rumen bacterial mutant having *ldh* and *pfl* gene, *ppc* gene disrupted.

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Applicants elect, with traverse, <u>Group II</u> consisting of claims 2, 8-9, and 31-32, drawn to rumen bacterial mutant having IdhA and pfl gene, pta gene and ackA gene disrupted to increase succinic acid production, not identified as being classified in any specific class or subclass.¹

Traversal of Restriction

In order for a Restriction Requirement to be made, there must be two or more independent or distinct inventions, which would provide a serious burden on the examiner if restriction is not required. Applicants do not agree that there are thirteen independent or distinct inventions in the presently pending claims.

Initially, the requirement for restriction is traversed, based on the examiner's failure to include class and subclass for each alleged Group set forth above. MPEP 817 provides an "Outline of Letter for Restriction Requirement" for the examiner. In subpart (A)(4), the instruction is to "[c]lassify each group." No classification of any of Groups 1-XIII is provided above. Provision of class and subclass groupings is essential to applicants' understanding of the identification of the Groups as independent and distinct inventions. Clarification of the requirement for Restriction is requested in this regard.

Additionally, claim 32 is not included in the above Requirement for Restriction. It is assumed that claim 32 should have been included in Group II, rather than "31-31," as claim 32 depends from claim 2, included within Group II. Clarification of the requirement for Restriction is requested in this regard.

MPEP 802.01 states that "independent" means that there is no disclosed relationship between the two or more inventions claimed. Inventions are "distinct" if, as claimed, they are not connected in at least one of design, operation, or effect. Independent or distinct inventions may be required to be restricted, however it is applicants' position that there are not independent or distinct inventions in the present claims.

Groups I-III are not independent or distinct inventions, as all three groups include mutants with mutated *IdhA* and *pfl* genes. In some of the mutants additional genes are mutated, but all mutants contain those two mutations in common. There is a relationship among the mutants of Groups I-III and they are connected in design (all have mutated *IdhA* and *pfl* genes) and effect (all mutants have genes disrupted to increase succinic acid production). Accordingly, Groups I-III are neither

¹ No class or sublclass categories were provided for any of the claims in the Requirement for Restriction.

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independent nor distinct from one another and restriction should not be required among Groups I-III.

Groups IV-VI are not independent or distinct inventions, as all three groups recite methods of producing mutants that contain mutated *ldhA* and *pfl* genes. In some of the methods, additional genes are mutated in addition to *ldhA* and *pfl*, but all methods produce a mutant containing those two mutations in common. As such, there is a relationship among the methods of Group IV-VI, in that all produce mutants with some mutations in common. There is also a connection in operation and effect of the methods of Groups IV-VI, in that all result in mutants that contain mutated *ldhA* and *pfl* genes. Accordingly, Groups IV-VI are neither independent nor distinct from one another and restriction should not be required among Groups IV-VI.

Additionally, it is clear, as set forth in the MPEP 802.01(II) that "process and product made" claims are "related (i.e., not independent) if they are disclosed as connected in at least one of design..., operation..., or effect." Therefore the above Groups of product and process made (Groups I-VI) are not independent inventions.

Groups VII-X are not independent or distinct inventions, as all four groups recite vectors containing a particular gene disruption. There is a relationship among the vectors of Groups VII-X in that they all contain a particular gene disruption and all of the claimed vectors are connected in design (all have a particular mutated gene). Accordingly, Groups VII-X are neither independent nor distinct from one another and restriction should not be required among Groups VII-X.

Groups XI-XIII are not independent or distinct inventions, as all three groups recite methods of producing succinic acid using mutants that contain mutated *ldhA* and *pfl* genes. In some of the methods, additional genes are mutated in addition to *ldhA* and *pfl*, but all methods produce succinic acid utilizing a mutant containing those two mutations in common. As such, there is a relationship among the methods of Groups XI-XIII, in that all produce succinic acid utilizing mutants with at least *ldhA* and *pfl* gene mutations. There is also a connection in operation and effect of the methods of Groups XI-XIII, in that all result in production of succinic acid and all utilize mutants that contain mutated *ldhA* and *pfl* genes. Accordingly, Groups XI-XIII are neither independent nor distinct from one another and restriction should not be required among Groups XI-XIII.

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Even if all of the above-identified groups are independent or distinct, search of all claims of the application would not pose a serious burden on the examiner if restriction is not required. It appears that Groups I-III, Groups IV-VI, Groups VII-X, and Groups XI-XIII would each have been in the same class and subclass, if such classification had been provided. Search of each set of Groups would therefore not pose a serious burden.

Furthermore, search of <u>all</u> of Groups I-XIII together would not pose a serious burden on the examiner, due to the relatedness of the claims, as discussed above.

Rejoinder

In the event that the Requirement for Restriction is made final with Groups I-XIII, applicants responsively request rejoinder of method claims 12, 14, and 18-20 (Group V) and 28-30 (Group XII) under the provisions of MPEP 821.04 upon confirmation of allowable subject matter of the composition claims 2, 8-9, and 31-32 of Group II.

Such rejoinder would be fully proper under these circumstances.2

In the present application, elected claims 2, 8-9, and 31-32 are directed to rumen bacterial mutants and claims 12, 14, 18-20, and 28-30 are directed to methods for making and using such mutants. Consistent with the provisions of the MPEP 821.04, when the product claims 2, 8-9, and 31-32 of Group II are subsequently found allowable, any withdrawn method of making and/or using claims (Groups V and XII) would be properly rejoined for examination.

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When an application as originally filed discloses a product and the process for making and/or using such product, and only the claims directed to the product are presented for examination, when a product claim is found allowable, Applicants may present claims directed to the process of making and/or using the patentable product for examination through the rejoinder procedure in accordance with MPEP §821.04, provided that the process claims depend from or include all the limitations of the allowed product claims.

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Conclusion

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In response to the Requirement for Restriction dated July 31, 2006, Applicants have provisionally elected, with traverse, Group II, claims 2, 8-9, and 31-32, drawn to "rumen bacterial mutant having IdhA and pfl gene, pta gene and ackA gene disrupted to increase succinic acid production," and not identified as being classified in any class or subclass.

No fees are believed to be due for the filing of this paper. However, should any fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any additional issues remain, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same, in order that the prosecution of this application is expedited.

5/30/07

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Respectfully submitted,

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